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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,738	10/22/2001	Stanley R. Conston	08251-036001	1836

7590 06/02/2004

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EXAMINER

IMAM, ALI M

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,738	CONSTON ET AL.	
	Examiner	Art Unit	
	Ali Imam	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/2/4 (RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/2/4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 are rejected under 35 U.S.C. 102(e) as being anticipated by Hossack et al. (US 5,944,666).

In regard to claims 1 and 15, Hossack teaches in col. 2, line 27 - col. 6, line 45, a method delivering contrast agent into a blood vessel comprising the steps of introducing an agent-loaded microbubble population into a region of interest (RIO); applying an ultrasonic signal using transducers embodied within a distal portion of a cannula to the RIO at a power intensity sufficient to induce microbubble rupture; and maintaining the power intensity until at least a substantial number of microbubble are ruptured.

In regard to claims 2 and 3, Hossack teaches in col. 3, lines 60-65, the steps of monitoring microbubble movement.

In regard to claim 4, Hossack teaches that the microbubbles' diameter is about 2 microns.

In regard to claims 5-8, ultrasonic microbubbles are inherently comprises an outer layer of biologically compatible amphiphilic material and an inner layer of a biodegradable polymer comprising the claimed various polymer selections.

In regard to claims 9-11, it would be a matter of user's discretion to introduce the contrast agent into a blood vessel of a heart or kidney or liver.

In regard to claim 12, the specific mechanical index is regulated by the FDA and therefore, it is anticipated that Hossack's invention would provide a mechanical index between 0.1 and 1.9.

In regard to claim 13, Hossack teaches a plurality of transducers (col. 2, lines 57-68) focused at the RIO and emitting a beam sufficient to rupture the microbubbles.

In regard to claim 14, since Hossack's invention monitors and tracks the movement and mixing of microbubbles in the RIO, it is inherent that the rate of release would also be determined.

In regard to claims 16-22, it would be a matter of user's discretion to introduce appropriate drugs to the heart to perform intended treatment.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Unger et al. (US 6,071,495) teaches various compositions of ultrasonic microbubble contrast agents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Imam whose telephone number is 703-305-0028. The examiner can normally be reached on Mon. - Th., 8:00- 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ali Imam
Primary Examiner
Art Unit 3737

AMI
5/31/4